

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

Friday, July 20, 2001

- 8:30 Call to Order/ Steve R. Byrn, Ph.D.
Conflict of Interest Nancy Chamberlin, Pharm.D, Exec. Sec.
- 8:35 **Clinical Pharmacology**
- 8:35 Introduction and Background Larry Lesko, Ph.D.
- 8:45 Overview of draft Lactation Studies Guidance Arzu Selen, Ph.D.
- 8:55 Nonclinical and clinical methods to determine the amount of drug in breast milk Shinya Ito, M.D.
- Drug Transfer into Milk: Clinical Methods and Issues Patrick J. McNamara, Ph.D.
- 9:25 Committee and Panel Discussion
Issue: Methods to determine drug transfer into breast milk and interpretation of data
- 10:00 Break
- 10:15 Open Public Hearing
- 11:15 **Complex Drug Substances - Liposome Drug Products**
- 11:15 Introduction Mei-Ling Chen, Ph.D.
- 11:20 Overview of Liposome Drug Products Francis J. Martin, Ph.D.
- 11:45 Pharmaceutical Equivalence: CMC Issues Arthur Shaw, Ph.D.
- 12:00 Bioavailability and Bioequivalence:
Biopharmaceutics Issues Kofi Kumi, Ph.D.
- 12:15 Committee Discussion
Topic #1 - PE issues
Topic #2 - BA/BE issues
- 12:45 Adjourn